

Office Action Summary

Application No.

09/445,963

Applicant(s)

TANAKA ET AL.

Examiner

Natalie A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 is/are allowed.
- 6) ☒ Claim(s) 5, 6 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s) _____.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's response to the Office Action sent on 2 February 2001 in Paper No. 5 is acknowledged. Claims 1-4 are cancelled, new claims 5-11 are added, the specification amended to include the current status of all nonprovisional parent applications referenced, and the claim heading corrected.
2. The statement of statutory basis of all rejections has been included in the previous Office Action and will not be included herein.

Claim Rejections - 35 USC § 112 Withdrawn

3. Rejection of claims 1-4 under 35 U.S.C.112, second paragraph for the use of ambiguous language is withdrawn in view of the cancellation of those claims.
4. Rejection of claims 8-9 under 35 U.S.C.112, first paragraph is withdrawn in view of amendments. The removal of "diagnosing" and addition of "detecting" to amended claim 8 obviates the indefinite rejection found in paragraph 4 of the previous office action.

Claim Rejections - 35 USC § 112 Maintained

5. Rejection of new claims 7, 9, and 11 under 35 U.S.C.112, second paragraph is maintained as was set forth in the previous office action in the rejection of claims 3 and 4 (paragraph 2) in the recitation of a diagnostically and pharmaceutically acceptable carrier. The specification does not indicate that these terms may be used interchangeably.

Claim Rejections - 35 USC § 102 Withdrawn

6. Rejection of claims 1-2 under 35 U.S.C. 102(b) (paragraph 6) is withdrawn due to the cancellation of the claims.

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7. Rejection of claim 2 under 35 U.S.C. 102(b) (paragraph 7) is withdrawn due to the cancellation of that claim.

Claim Rejections - 35 USC § 102 Maintained

8. Rejection of new claims 5 and 6 under 35 U.S.C. 102(b) is maintained as was set forth in the previous office action for the rejection of claims 3 and 4 (paragraph 8). The traversal of this rejection is based on the grounds that Kajiwara does not use ¹³C-ALA for the detection or diagnosis in the sense of the present invention. Applicant's arguments have been fully considered but they are not persuasive because Kajiwara teaches the claimed isotope; the intended use is not taken into account for a product claim.

Claim Rejections - 35 USC § 103 Maintained

9. Rejection of new claims 8 and 9 under 35 U.S.C. 103(a) is maintained as was set forth in the previous office action for the rejection of claim 1 (paragraph 10). The traversal of this rejection is based on the grounds that compounds are structurally analyzed with NMR and Jichlinski, et al. and Jaffe, et al. both relate to the treatment of a malignant tumor. Applicant's arguments have been fully considered but they are not persuasive because NMR detects the presence of the claimed isotope and a tumor must first be detected before it may be treated. In addition, the specification states that the best mode of action for carrying out the invention is when a carbon or nitrogen atom of 5-aminolevulinic acid is replaced with an isotope and detected using nuclear magnetic resonance (p. 4-5). Furthermore, the working example (p. 25-26) used NMR to detect malignant tumors. The claims may be allowable if drawn to a method of detecting and photokinetically treating malignant tumors, as the art does not read on a agent/composition, which is able to do both.

10. Rejection of new claims 10 and 11 under 35 U.S.C. 103(a) are maintained as was set forth in the previous office action for the rejection of claims 2 and 3 (paragraphs 7 and 8) under 102 (b), as being unpatentable over Kajiwara (JP 02111747, 1990) ^{in view of} and Kennedy, et al. (1994). Kajiwara teach ¹³C-labeled 5-aminolevulinic acid, but does not teach to use it in photokinetic

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treatment of cancer. However, Kennedy, et al. teach photokinetic treatment of tumors using labeled 5-aminolevulinic acid. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the teachings of Kajiwara and Kennedy to use the method as claimed.

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

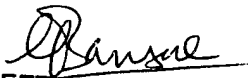
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph.D.

August 20, 2001


GEETHA P. BANSAL
PRIMARY EXAMINER